



UNITED STATES PATENT AND TRADEMARK OFFICE

clg
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,391	07/03/2003	Harmut Kueppers	029300.52512US	3207
23911	7590	08/10/2006	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,391

Applicant(s)

KUEPPERS ET AL.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Action Summary

The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicant's amendment.

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. (WO 99/20260 A2) is maintained for the reasons stated in the previous Office Action.

The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (WO 99/20260 A2) as applied to claims 1-4 above, and further in view of Venkatesh et al. (U.S. Patent No. 6,517,871 B1) is maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed May 18, 2006 have been fully considered but they are not persuasive. **With regard to 35 U.S.C. 102(b) rejection** over Montgomery, Applicants essentially argue that Montgomery et al. indicate their invention would be useful in including treating wasting disease, promoting trainability and fitness, and altering body composition and that example 2 of Montgomery et al. describe the treatment of military recruits with the AT1 antagonist Losartan which is different from the

Art Unit: 1617

presently-claimed invention. This is not persuasive because Montgomery et al. clearly teach the AT1 receptor antagonists including eprosartan is useful for the treatment of prevention of stroke or its recurrence and because Montgomery et al. in his claims 2, 20 and 21, specifically teaches that eprosartan as one of AT1 receptor antagonists useful for the treatment or prevention of stroke or its recurrence. Applicants argue that the presently claimed invention relates to inhibiting a subsequent stroke and the term "subsequent stroke" refers to a stroke that occurs after a primary stroke and that is a consequence of the condition the patient is in as a result of the earlier stroke, and to arrive at this invention one must first realize that pathology of patients who have already suffered from a stroke is different from those who have not. This is not persuasive because it is noted that Montgomery et al. teach that AT1 receptor antagonist including eprosartan is useful for the prevention or the treatment of stroke or **its recurrence**. This teaching of treatment of "**recurrence**" of **stroke** clearly anticipates Applicants limitation of "subsequent stroke". Therefore, Applicants claimed subject matter of inhibiting a subsequent stroke in a patient who has previously suffered at least one earlier stroke comprising administering AT1 receptor antagonist including eprosartan. is deemed anticipated by the teaching of Montgomery et al. comprising utilization of same active agent for the same treatment. **With regarding 35 U.S.C. 103(a) rejection**, Applicants argue that the cited combination of references fails to teach or suggest each and every claimed limitation. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion,

Art Unit: 1617

or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one of ordinary skill in the art to employ eprosartan mesylate for the treatment of preventing stroke or its recurrence as taught by Montgomery et al. because eprosartan mesylate is readily available and well known salt of eprosartan as taught by Venkatesh et al. One of ordinary skill in the art would have been motivated to employ eprosartan mesylate for the prevention and treatment of reoccurrence of stroke in order to conveniently employ eprosartan mesylate formulation readily available and well known by Venkatesh et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of November 18, 2005 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 102

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. (WO 99/20260 A2).

Montgomery et al. teach the AT1 receptor antagonist including losartan, valsartan, irbesartan, candesartan, eprosartan, tasosartan and telmisartan useful for the treatment or prevention of stroke or its recurrence. (abstract, page 7, line 21, page 8, lines 1-10, page 9, lines 8-14, claims 2, 20 and 21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (WO 99/20260 A2) as applied to claims 1-4 above, and further in view of Venkatesh et al. (U.S. Patent No. 6,517,871 B1).

Montgomery et al. as applied as before.

Montgomery et al. do not teach the specific salt set forth in claim 5.

Art Unit: 1617

Venkatesh et al. teach a formulation comprising eprosartan mesylate as well known salt form of eprosartan. (abstract, column 1).

It would have been obvious to one of ordinary skill in the art to employ eprosartan mesylate for the treatment of preventing stroke or its recurrence as taught by Montgomery et al. because eprosartan mesylate is readily available and well known salt of eprosartan as taught by Venkatesh et al. One of ordinary skill in the art would have been motivated to employ eprosartan mesylate for the prevention and reoccurrence of stroke in order to conveniently employ eprosartan mesylate formulation readily available and well known by Venkatesh et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1617

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

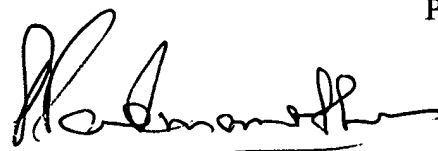
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/612,391

Art Unit: 1617

Page 8

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line drawn underneath it.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
July 26, 2006